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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Shone *et al.*

Appl. No. 09/831,050

International Filing Date:
November 5, 1999

For: **Delivery of Superoxide Dismutase to Neuronal Cells**

Confirmation No. 8265

Art Unit: 1647

Examiner: Wegert, S.L.

Atty. Docket: 1581.0800000/RWE

Reply To Restriction Requirement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated April 11, 2003, requesting an election of one invention to prosecute in the above-referenced patent application, Applicant hereby provisionally elects, *with traverse*, to prosecute the invention of Group I, represented by claims 25, 29-33, 36 and 43. Applicants note that claim 42, which was not included in a group by the Examiner, appears to also be a member of Group I. Further, it is unclear in which groups certain claims are included, as claim 29 is grouped with both I and II, and claim 36 is grouped in I and IV. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

The Examiner alleged that Group I lacks a special technical feature distinguishing it from the prior art, specifically Figueiredo *et al.* Applicants respectfully traverse this statement. All claims in group I, as represented by claims 25 and 36, clearly require that the linker between the SOD and the targeting component be cleavable. In Figueiredo *et al.*, the linker is specifically not cleaved. On page 550, second column, second full

paragraph, the authors state "the linkage between SOD and TC is intact (see Table 1 and Results)." Table 1 shows the results from assays using both anti-TC and anti-SOD antibodies. In the Results, on page 548, at the top of the second column, the authors state "[t]his suggests that most of the TC in the hypoglossal nucleus is still linked to SOD 3 days after injection. . ." Clearly the fusion protein of Figueiredo *et al.* is not cleavable, nor is there any discussion of using a cleavable linker. Therefore, this reference does not meet the limitations of the claims, and Applicants respectfully traverse the Examiner's statement that "none of the other claimed inventions can share a special technical feature with the first claimed invention."

The Examiner alleged that groups I, II, IV, and V are independent and distinct by virtue of have differences in structure and function with independent utilities. Applicants respectfully traverse this allegation. Group I (claims 25, 29-33, 36, 42 and 43) is directed to a composition containing SOD attached via a cleavable linker to a neuronal cell targeting component. Group II is defined as claims 26-29 and 37-39. Claims 26-28 are dependent from the generic claim 25 of group I, and merely add an additional limitation of targeting the SOD to mitochondria within neuronal cells. Claim 29 is also dependent from claim 25, but adds the limitation that the SOD is bacterial. It is unclear why claim 29 is restricted to both groups I and II. However, claims 26-29 are subgeneric to the generic claim 25, incorporate all the limitations of claim 25, and do not have utilities independent from claim 25. Therefore, the groups are not independent and distinct under 35 U.S.C. § 121 or 37 C.F.R. § 1.142(a), as defined in MPEP 802.01 (Eighth ed., Rev.

February, 2003). Therefore, Applicants respectfully requests the restriction be withdrawn and all claims be considered and allowed.

Claims 37-39, also grouped in II, are drawn to polypeptide comprising bacterial SOD linked to a mitochondrial targeting sequence. As both group I and claims 37-39 are directed to SOD, they are related. A search for SOD would necessarily encompass the subject of both sets of claims, presenting no serious burden for examination. The Examiner has presented no evidence outlined by MPEP 808.02 supporting a reason for dividing among the related inventions. Therefore, Applicants respectfully requests the restriction be withdrawn and all claims be considered and allowed.

Group IV, defined by the Examiner as claim 36, is included in the Examiner's definition of group I (claims 25, 29-33, 36, and 43). It is unclear what the Examiner intended, and the Applicants respectfully request that all claims be considered and allowed. *See* MPEP 814.

Group V, represented by claims 40 and 41, is directed to a nucleotide encoding the peptide of group II. Assuming *arguendo* that this group is distinct, it is related, and a search for the polypeptide of group II would necessarily encompass the same publications for group V. Publications directed to a protein, for example, routinely describe the nucleic acid encoding it and vice versa. Therefore, it would be a simple matter for the Examiner to search for both groups. Therefore, Applicants respectfully requests the restriction be withdrawn and all claims be considered and allowed.

The Examiner stated that the invention of group III are related to the inventions of groups I, II, and V as product and process of use. For such a restriction, the Examiner noted that either or both of the following must be shown: (1) the process for using the product *as claimed* can be practiced with another materially different product, or (2) the product *as claimed* can be used in a materially different process of using that product [emphasis added]. Claims 25 and claims depending thereon (groups I and II) are directed to compositions for delivery of a specific agent to neuronal cells. The Examiner stated the polypeptide of groups I and II can be used to generate antibodies. Since neuronal cells do not manufacture antibodies, it is unclear how the compositions of groups I and II can be used to generate antibodies. Further, the Examiner stated that the invention of group V may be used for gene therapy. Assuming *arguendo* this is true, gene therapy can be considered the administration of a therapeutically effective of a nucleic acid, usually to produce a protein *in vivo*. Therefore, Applicants respectfully requests the restriction be withdrawn and all claims be considered and allowed.

Finally, the Examiner alleged that the inventions of groups III and IV are unrelated. As noted *supra*, it is unclear what the Examiner believes is the invention of group IV as the only claim in that group (claim 36), is expressly listed in group I as well. Therefore, Applicants respectfully requests the restriction be withdrawn and all claims be considered and allowed.

Applicants retain the rights to petition from the restriction requirement under 37 C.F.R. § 1.144.

Reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

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